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EXAMINER	
RAJAN, KAI	

ART UNIT	PAPER NUMBER
3769	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/625,633	HUTCHINSON ET AL.	
	Examiner	Art Unit	
	Kai Rajan	3769	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 July 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5-14,16,17,28,68,69 and 71-84* is/are pending in the application.

4a) Of the above claim(s) *13,14* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5-12,16,17,28,68,69 and 71-84* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Examiner acknowledges the reply filed July 16, 2009. Furthermore, the case has been transferred to Examiner Kai Rajan for further prosecution.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 6-8, 72-75 and 81-84 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

Claims 6 – 8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Claims 6 – 8 positively recites limitations that overlap statutory classes. In this case, the applicant has positively recited *a method and an apparatus* in the same claim, such as "editing, deleting, adding." See MPEP 2173.05(p) II.

Claims 72-75 and 81-84 are drawn to a process. Under 35 U.S.C. §101 a process must 1) be tied to another statutory class (such as a particular apparatus) or 2) transform underlying subject matter (such as an article or materials) to a different state or thing. The claimed process steps do not transform underlying subject matter. Thus, to qualify as a 35 U.S.C. § 101 statutory process, the claims should positively recite the other statutory class (apparatus or thing) to which it is tied, for example by identifying the apparatus that accomplishes the method steps. Examiner notes that while some extra-solution activity is done with an apparatus in the form of sensors

collecting the physiological data, this is an insignificant step and is not sufficient to pass the test. Furthermore, "a logic" does not recite an apparatus or structure that accomplishes method steps. Rather, "logic" is software or algorithms performed on an apparatus, and without more, is not a tangible apparatus. The Examiner recommends positively claiming a processor performing the method steps, pending support from the written disclosure.

http://www.uspto.gov/web/offices/pac/dapp/opla/preognotice/section_101_05_15_2008.pdf

http://www.uspto.gov/web/offices/pac/dapp/opla/documents/bilski_guidance_memo.pdf

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 74-75 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The Examiner is unable to find support in the original disclosure for "a geographically diffuse manner" (claim 74).

Claim 75 is rejected based on its dependence on claim 74.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 74-75 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Regarding claim 74, the limitation "a geographically diffuse manner" in lines 3 and 14 is indefinite because it is unclear from the claim language what exactly is meant by geographically diffuse or from what original location/point the claimed point is geographically diffuse. Additionally, the specification does not provide any description or definition as to the scope of the phrase "geographically diffuse".

Claim 75 is rejected based on its dependence on claim 74.

Note to Applicant Regarding Claim Interpretation

The terms "for," "configured to," and "adapted to" in the claim(s) may be interpreted as intended use. Intended use/functional language does not require that reference specifically teach the intended use of the element. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 3, 5 – 12, 16, 68, 69, and 71 – 84 are rejected under 35 U.S.C. 102(e) as being anticipated by Nunome U.S. Patent No. 6,497,657 B2.

1. A patient physiologic monitoring assembly comprising:

a plurality of sensors that generate a real-time physiologic data stream, said real-time physiologic data stream including a plurality of physiologic variables (Column 5 lines 5 – 50 physical – information obtaining devices);

a first logic rule set including a plurality of logic rules for interpreting the plurality of physiologic variables (Column 7 lines 35 – 61 preliminary – diagnosis means);

a second logic rule set including a plurality of logic rules for interpreting the physiologic variables (Column 7 lines 46 – 61 doctor – side terminal devices); and

a controller that receives said real-time physiologic data stream, said controller including a logic adapted to cross reference said plurality of physiologic variables with the first logic rule set and second logic rule set (Column 5 lines 64 – 67, column 6 lines 1 – 33 computer receives signals from physical-information obtaining devices and is networked with doctor-side devices to receive diagnoses); and

generate at least a first diagnostic interpretation of said plurality of physiologic variables utilizing said first logic rule set and a second diagnostic interpretation of said plurality of

physiologic variable utilizing the said second logic rule set (Column 7 lines 10 – 45, column 8 lines 43 – 47 patient – side terminal device processes collected data and generates first diagnosis, and receives and displays second diagnosis from doctor-side terminal).

2. A patient physiologic monitoring assembly as described in claim 1, wherein said logic is further adapted to display said first and second diagnostic interpretations on a display element (Column 7 lines 10 – 45, column 8 lines 43 – 47 patient – side terminal receives and displays second diagnosis from doctor-side terminal).

3. A patient physiologic monitoring assembly as described in claim 1, wherein said logic is further adapted to select said first logic rule set and said second logic rule set from a rules database, said rules database including a plurality of logic rule sets (Column 3 lines 40 – 56 reference ranges are stored in the patient-side terminals for different users, and a reference range is selected for the particular user.).

5. A patient physiologic monitoring assembly as described in claim 3, wherein said logic is further adapted to modify one of said plurality of logic rules within said first logic rule set (Column 8 lines 16 – 25, 48 – 65 reference – range changing means and registering means changes rules used to evaluate collected data).

6. A patient physiologic monitoring assembly as described in claim 5, wherein said modification comprises editing one of said plurality of logic rules (Column 8 lines 16 – 25, 48 –

65 reference – range changing means and registering means changes rules used to evaluate collected data).

7. A patient physiologic monitoring assembly as described in claim 5, wherein said modification comprises deleting one of said plurality of logic rules (Column 8 lines 16 – 25, 48 – 65 reference – range changing means and registering means changes rules used to evaluate collected data).

8. A patient physiologic monitoring assembly as described in claim 5, wherein said modification comprises adding a new logic rule to said first logic rule set (Column 8 lines 16 – 25, 48 – 65 reference – range changing means and registering means changes rules used to evaluate collected data).

9. A patient physiologic monitoring assembly as described in claim 3, wherein said logic is further adapted to add a new logic rule set to said rules database (Column 8 lines 16 – 25, 48 – 65 reference – range changing means and registering means changes rules used to evaluate collected data).

10. A patient physiologic monitoring assembly as described in claim 1, further comprising a plurality of networked medical facilities in communication with said controller such that said first logic rule set may be received from any of said plurality of networked medical

facilities (Column 7 lines 46 – 61, column 8 lines 16 – 25 doctor-side terminals receive preliminary diagnosis and can view reference ranges used).

11. A method for providing diagnostic aid to a clinician monitoring the medical condition of a patient, the method comprising:

storing a first and a second set of rule-based algorithms, the first and second sets of rule-based algorithms, generating different diagnostic interpretations of the same physiological data (Column 5 lines 64 – 67, column 6 lines 1 – 33, column 7 lines 35 – 61 preliminary diagnosis means and doctor-side terminals);

acquiring a physiological data stream from at least one sensor connected to the patient (Column 5 lines 5 – 50 physical – information obtaining devices);

applying with a logic of a controller at least one rule-based algorithm from a-the first set of the rule-based algorithms to the acquired physiological data stream (Column 7 lines 35 – 61 preliminary – diagnosis means);

generating a first diagnostic interpretation with the controller based on the application of the at least one rule-based algorithm from the first set to the acquired physiological data stream; displaying the first diagnostic interpretation to the clinician (Column 7 lines 10 – 16, 35 – 61 preliminary – diagnosis means creates a diagnosis which is displayed on the patient-side terminal);

applying with the logic at least one rule-based algorithm from the second set of rule-based algorithms to the acquired physiological data stream (Column 7 lines 46 – 61 doctor – side terminal devices);

generating with the controller a second diagnostic interpretation based on the application of the at least one rule-based algorithm from the second set to the acquired physiological data stream (Column 7 lines 10 – 45, column 8 lines 43 – 47 patient – side terminal device receives and displays second diagnosis from doctor-side terminal); and

displaying the second diagnostic interpretation to the clinician (Column 8 lines 30 – 47).

12. The method of claim 11, further comprising determining the first set of rule based algorithms to apply to the acquired physiological data stream comprising displaying a list of choices to a clinician and receiving a clinician input indicative of a selection made by the clinician (Column 8 lines 31 – 47 doctor input).

16. The method of claim 11, further comprising:

storing the first and second set of rule-based algorithms at a data storage device remote to the controller (Column 8 lines 16 – 25, 48 – 65 doctor-side terminals); and

transferring the first and second set of rule-based algorithms from the data storage device (Column 8 lines 16 – 25, 48 – 65 reference – range changing means and registering means send reference ranges to the patient-side terminal).

68. A patient physiologic monitoring assembly as described in claim 2, wherein said logic is further adapted to receive a selection of the first diagnostic interpretation or the second diagnostic interpretation from a clinician (Column 7 lines 10 – 45, column 8 lines 43 – 47 patient – side terminal device receives and displays second diagnosis from doctor-side terminal).

69. The method of claim 11 wherein the plurality of rules of the first rule set are directed towards a general diagnostic interpretation identifying a target body system and the plurality of rules of the second rule set are directed towards creating a specific diagnostic interpretation of a condition within a targeted body system (Column 7 lines 35 – 45, column 8 lines 30 – 47 preliminary-diagnosis means compares data to reference-ranges and determines whether diagnosis from doctor-side terminal is needed).

71. The method of claim 69 wherein the general diagnostic interpretation identifies the cardiac system and the specific diagnostic interpretation identifies a cardiological condition (Column 5 lines 5 – 63).

Claims 72 – 84 are rejected by the system and method of Nunome as rejected above, in at least column 3 lines 40 – 56, column 5 lines 64 – 67, column 6 lines 1 – 33, column 7 lines 10 – 61, and column 8 lines 16 – 65.

Claims 1 – 3, 10 – 12, 16, 17, 28, and 68 are rejected under 35 U.S.C. 102(e) as being anticipated by Yasushi et al. U.S. Patent No. 6,485,418 B2.

1. A patient physiologic monitoring assembly comprising:

a plurality of sensors that generate a real-time physiologic data stream, said real-time physiologic data stream including a plurality of physiologic variables (Yasushi column 2 lines 11 – 50 multiple portable terminal devices 1 contain heart beat sensors 11);

a first logic rule set including a plurality of logic rules for interpreting the plurality of physiologic variables (Yasushi column 4 lines 33 - 64 first center device diagnosis);

a second logic rule set including a plurality of logic rules for interpreting the physiologic variables (Yasushi column 4 lines 65 – 67, column 5 lines 1 – 17 second center device diagnosis); and

a controller that receives said real-time physiologic data stream, said controller including a logic adapted to cross reference said plurality of physiologic variables with the first logic rule set and second logic rule set (Column 4 lines 21 – 53 first center device 3 receives data from portable terminal devices, applies first diagnosis, and receives second diagnosis); and

generate at least a first diagnostic interpretation of said plurality of physiologic variables utilizing said first logic rule set and a second diagnostic interpretation of said plurality of physiologic variable utilizing the said second logic rule set (Yasushi column 4 lines 21 – 67, column 5 lines 1 – 18. Yasushi et al. teach that the diagnoses performed by operators can be replaced by automatic comparisons and diagnoses performed by the devices.).

2. A patient physiologic monitoring assembly as described in claim 1, wherein said logic is further adapted to display said first and second diagnostic interpretations on a display element (Yasushi column 4 lines 21 – 67, column 5 lines 1 – 18 conditions are displayed on a monitor).

3. A patient physiologic monitoring assembly as described in claim 1, wherein said logic is further adapted to select said first logic rule set and said second logic rule set from a rules database, said rules database including a plurality of logic rule sets (Yasushi column 4 lines 21 – 67, column 5 lines 1 – 18).

10. A patient physiologic monitoring assembly as described in claim 1, further comprising a plurality of networked medical facilities in communication with said controller such that said first logic rule set may be received from any of said plurality of networked medical facilities (Yasushi column 3 lines 8 – 17, see also figure 4).

11. A method for providing diagnostic aid to a clinician monitoring the medical condition of a patient, the method comprising:

storing a first and a second set of rule-based algorithms, the first and second sets of rule-based algorithms, generating different diagnostic interpretations of the same physiological data (Yasushi column 4 lines 21 – 67, column 5 lines 1 – 18 first and second center devices);

acquiring a physiological data stream from at least one sensor connected to the patient (Yasushi column 2 lines 11 – 50 multiple portable terminal devices 1 contain heart beat sensors 11);

applying with a logic of a controller at least one rule-based algorithm from the first set of the rule-based algorithms to the acquired physiological data stream (Yasushi column 4 lines 33 - 64 first center device diagnosis);

generating a first diagnostic interpretation with the controller based on the application of the at least one rule-based algorithm from the first set to the acquired physiological data stream; displaying the first diagnostic interpretation to the clinician (Yasushi column 4 lines 21 – 67, column 5 lines 1 – 18. Yasushi et al. teach that the diagnoses performed by operators can be replaced by automatic comparisons and diagnoses performed by the devices.);

applying with the logic at least one rule-based algorithm from the second set of rule-based algorithms to the acquired physiological data stream (Yasushi column 4 lines 65 – 67, column 5 lines 1 – 17 second center device diagnosis);

generating with the controller a second diagnostic interpretation based on the application of the at least one rule-based algorithm from the second set to the acquired physiological data stream (Yasushi column 4 lines 21 – 67, column 5 lines 1 – 18. Yasushi et al. teach that the diagnoses performed by operators can be replaced by automatic comparisons and diagnoses performed by the devices.); and

displaying the second diagnostic interpretation to the clinician (Yasushi column 4 lines 21 – 67, column 5 lines 1 – 18 conditions are displayed on a monitor).

12. The method of claim 11, further comprising determining the first set of rule based algorithms to apply to the acquired physiological data stream comprising displaying a list of choices to a clinician and receiving a clinician input indicative of a selection made by the clinician (Yasushi column 4 lines 21 – 67, column 5 lines 1 – 18).

16. The method of claim 11, further comprising:

storing the first and second set of rule-based algorithms at a data storage device remote to the controller (Yasushi column 4 lines 33 – 67, column 5 lines 1 – 17); and

transferring the first and second set of rule-based algorithms from the data storage device (Yasushi column 4 lines 33 – 67, column 5 lines 1 – 17).

17. The method of claim 11, wherein generating a response based on the application of at least one of the plurality of rule-based algorithms comprises generating an alarm (Yasushi column 5 lines 32 – 62).

28. The method of claim 72, further comprising generating a certainty score for each of the general diagnostic interpretations (Yasushi column 3 lines 41 – 53 step s10 determines if the diagnosis is doubtful or not).

68. A patient physiologic monitoring assembly as described in claim 2, wherein said logic is further adapted to receive a selection of the first diagnostic interpretation or the second diagnostic interpretation from a clinician (Yasushi column 4 lines 33 – 67, column 5 lines 1 – 17).

Response to Arguments

Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is (571)272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Johnson can be reached on 571-272-4768. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Kai Rajan/
Examiner, Art Unit 3769

/Michael C. Astorino/
Primary Examiner, Art Unit 3769

November 9, 2009